

TO: See Distribution List

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THROUGH: Anita Okrend, Chief
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SUBJECT: Amended Microbiological Data Program Plan (January – September 2001)

This document replaces the initial Microbiological Data Program (MDP) Plan dated February 22, 2001. This Program Plan (Plan) serves as the current Statement of Work for the period January 2001 through September 2001 for each State participating in the MDP. This document also stipulates work assignments for the Federal facility participating in MDP. The contents of the Plan have been discussed with the Centers for Disease Control and the Food and Drug Administration, and approved by Robert Epstein, Acting Deputy Administrator of the Agricultural Marketing Service (AMS), Science and Technology Program (S&T). Amendments to the Plan include, 1) number of sub-samples collected; 2) sample collection dates; 3) sample weight requirements; and 4) removal of *Listeria Monocytogenes* testing. In addition, the attached Laboratory and Sampling Workload and the Distribution List reflect the program amendments as well as recent personnel changes in the California Department of Pesticide Regulation. Please archive the original Plan which was distributed in February 2001.

I. ADMINISTRATIVE UPDATES

A. Personnel:

Program participants are reminded to keep MDP management informed of any critical equipment purchases, staffing issues, or expected increases in rent (due to laboratory or office renovation/relocation, etc.). This information is required under the terms of the MDP Cooperative Agreements (Section II, Responsibilities) between USDA and participating States. A blank copy of a Cooperative Agreement is enclosed.

B. Equipment:

The California, Colorado, Michigan, Washington, and Wisconsin laboratories can use MDP funds allocated to their State to lease the Vitek Immune Diagnostic Assay System (VIDAS) with the option to purchase at a later date. The New York laboratory can use NY State allocated MDP funds to upgrade its existing VIDAS

instrument. If validation is successful, BAX systems will be purchased by USDA for all eight State laboratories using MDP funds allocated to each State. Separate arrangements will be made to purchase this system for the AMS Eastern Laboratory (EL). Florida, New York, Ohio, and the EL will perform side-by side (i.e., Cultural Methodology vs. BAX) evaluations prior to full implementation of the BAX systems by all laboratories.

C. MDP Federal/State Meeting:

This document incorporates minutes from a MDP Planning Meeting held January 10-11, 2001, in Tallahassee, Florida (see Feb. 22, 2001, Program Plan).

D. Quality Assurance (QA):

MDP's QA program will cover all aspects of data gathering, from sample collection to data reporting. QA protocols for sampling will be designed to protect sample integrity from the time of collection to the time of delivery at the testing facilities. QA protocols for testing will comprise all laboratory operations from the time of sample receipt to the time data are reported to MDP's central database which will be located in Manassas, Virginia. MDP laboratories will guarantee reported results by adherence to strict QA requirements. The QA program will be comprised of five elements: 1) Standard Operating Procedures (SOPs); 2) On-Site Reviews; 3) Proficiency Check Samples; 4) Quality Control Procedures (QC); and 5) Method Performance and Verification Procedures.

E. 2001 Proficiency Evaluation (PE) Program:

All laboratories will be required to participate in MDP's Check Sample Program. Check Samples will be issued by the USDA, AMS, EL to all participating laboratories performing microbiological analysis. Periodically prepared commodities containing known microorganisms will be sent to all participating laboratories and tested under the same conditions as routine samples. The resulting data are used to determine performance equivalency among the testing laboratories.

F. Standard Operating Procedures (SOPs):

Written SOPs will be in place to provide uniform administrative, sampling, and laboratory procedures. SOPs will be reviewed annually and, if necessary, revised to accommodate changes in the program.

G. Electronic Transfer of Data:

The Pesticide Data Branch staff is presently developing an interim software system using MS-Access97 which will provide participating State laboratories and the EL with the ability to enter the micro-organism monitoring data using interactive data

entry screens. Data will then be transmitted electronically to the MDP Staff Office using Internet e-mail facilities.

RDE Reengineering Project:

A software development firm will be contracted to reengineer the Remote Data Entry (RDE) system utilized by the Pesticide Data Program (PDP) during FY2001 to include modules for MDP. The reengineering project will be designed to ensure compatibility with new operating systems, to provide expanded capabilities for new PDP initiatives such as analysis of finished drinking water, to include provisions for shared resources with MDP, and to employ new technology wherever feasible for capturing and transferring electronic data. The new RDE system will likely be developed using Microsoft products such as Access and Visual Basic, allowing for royalty-free distribution of software that can be utilized with existing hardware.

II. PROGRAM SAMPLING AND TESTING UPDATES

A. Sample Collection

Trained inspectors in each State participating in MDP will collect samples using aseptic sampling techniques. Samples will be collected, packaged, and shipped in accordance with MDP Sampling SOPs. The normal monthly sampling rate will be based on 62 samples per commodity, as shown in Table 4 (see attachment). For MDP purposes, one sample equals three (3) individual sub-samples of a commodity from the same source. It is acceptable to collect more than one sample, per commodity, from the same site, provided different suppliers (i.e., growers, packers, and shippers) or countries are selected. Examples: 1) two samples of Leaf Lettuce if Romaine Lettuce is not available—one from Grower Smith and one from Grower Brown; or 2) two samples of imported tomatoes provided that the country of origin is not the same.

Initial Scheduled Commodities

Leaf Lettuce (LL) is scheduled to begin April 16, 2001. Each individual plant of leaf lettuce must weigh a minimum of 200 grams. Sample collection will be performed aseptically. A commodity fact sheet will be distributed to State Sampling Managers and MDP Technical Program Managers to ensure that sample collection, packaging, and shipping are performed in a uniform manner.

Romaine Lettuce (LR) is scheduled to begin April 16, 2001. Each individual plant of romaine lettuce must weigh a minimum of 200 grams. Sample collection will be performed aseptically. A commodity fact sheet will be distributed to State Sampling Managers and MDP Technical Program Managers to ensure that sample collection, packaging, and shipping are performed in a uniform manner.

Tomatoes (domestic) (TO) are scheduled to begin May 1, 2001. Each individual tomato must weigh a minimum of 100 grams (3 ½ - 4" diameter). Sample collection will be

performed aseptically. A commodity fact sheet will be distributed to State Sampling Managers and MDP Technical Program Managers to ensure that sample collection, packaging, and shipping are performed in a uniform manner.

Tomatoes (imported) (TO) are scheduled to begin May 1, 2001. Each individual tomato must weigh a minimum of 100 grams (3 ½ - 4" diameter). Sample collection will be performed aseptically. A commodity fact sheet will be distributed to State Sampling Managers and MDP Technical Program Managers to ensure that sample collection, packaging, and shipping are performed in a uniform manner.

Celery (CE) is scheduled to begin August 1, 2001. Each individual bunch of celery must weigh a minimum of 200 grams. A commodity fact sheet will be distributed to State Sampling Managers and MDP Technical Program Managers to ensure that sample collection, packaging, and shipping are performed in a uniform manner.

B. Testing

The organisms to be tested on all MDP commodities will be enumeration of generic *Escherichia coli* (*E. coli*) and presence or absence of *Salmonella*.

Samples will not be pre-washed nor outer leaves discarded prior to analysis. A surface wash of the sample will be performed. The wash will be performed on a rotary shaker at 160 RPM for 7 min.

A single tomato must weigh at least 100 grams. For lettuce and celery, a 200 gram sample will be used for testing. For analysis of lettuce, tomatoes, and celery, the amount of sample will be equivalent to the amount of diluent used [e.g., 200 grams of lettuce will be rinsed with 200 milliliters (mL) solution (Butterfield's Phosphate Diluent plus 1% Tween 80)]. The rinsate will be split for analysis of *E. coli* and *Salmonella* as follows: 33.3 mL for *E. coli*, and 50mL for *Salmonella*.

All laboratories will use the same isolation methods. *E.coli* will be isolated using the Most Probable Number (MPN) method for fecal coliforms. After the isolation and presumptive identification of the organisms, final species confirmation may be performed using cultural methods or any Association of Official Analytical Chemists (AOAC) Official Method.

For positive *E. coli* (generic) results, a swab will be sent to the USDA Agricultural Research Service (ARS) laboratory located in Athens, Georgia, for antibiotic resistance testing. ARS will send the isolate to Pennsylvania State University, located in University Park, Pennsylvania, for serotyping and to the EL. For positive *Salmonella* results, slant cultures should be sent to ARS and to the EL. The EL will be used as a culture collection and storage facility.

All shipment of cultures will follow the appropriate hazardous material shipping regulations as provided by AMS. The ARS laboratory will return properly addressed shipping containers.

Temperature Control: The laboratory is scheduled to receive three (3) individual sub-samples for each commodity. Each individual sub-sample will be tested for *E. coli* and *Salmonella*. Laboratory personnel will use an infrared thermometer to determine the surface temperature of the source sample. Laboratory personnel will check the freeze indicator located inside the shipping container to ensure that the sub-samples were not exposed to freezing temperatures.

Lettuce (Romaine and Leaf) sampling is scheduled to begin *April 16, 2001*. Participating laboratories will perform analysis for *E. coli* (generic) and *Salmonella*.

Tomato (Domestic and Imported) sampling is scheduled to begin *May 1, 2001*. Participating laboratories will perform analysis for *E. coli* (generic) and *Salmonella*.

Celery sampling is scheduled to begin *August 1, 2001*. Participating laboratories will perform analysis for *E. coli* (generic) and *Salmonella*.

C. Web Site for MDP Information:

An Internet Web Site for MDP will be developed and will include SOPs, contact information, program status, and other background information.

Attachments